UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SERGEANTS BENEVOLENT ASSOCIATION HEALTH & WELFARE FUND, individually and on behalf of itself and all others similarly situated, Plaintiff, v. ACTAVIS, PLC and FOREST LABORATORIES, LLC, MERZ PHARAMA GMBH & CO., KGAA, AMNEAL PHARMACEUTICALS, LLC, TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, INC., BARR PHARMACEUTICALS, INC., COBALT LABORATORIES, INC., UPSHER-SMITH LABORATORIES, INC., WOCKHARDT LIMITED, WOCKHARDT USA LLC, SUN PHARMACEUTICALS INDUSTRIES, LTD., DR. REDDY'S LABORATORIES LTD., and DR. REDDY'S LABORATORIES, INC, Defendants.	Civil Action No. 1:15-cv-06549-CM ECF Case

GENERIC DEFENDANTS'

OPPOSITION TO INDIRECT PURCHASER'S

MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT

I. Plaintiff's Motion to Amend The Complaint Should Be Denied As Futile

The "Second Amended Class Action Complaint" proffered by the Indirect Purchaser Plaintiff ("Plaintiff") fails to cure the defects of the earlier complaints. Plaintiff's October 18, 2018 "Motion For Leave To File Second Amended Cass Action Complaint" (ECF 150) should therefore be denied. "Motions to amend should generally be denied in instances of futility." *Smith v. Manhattan Club Timeshare Ass'n, Inc.*, 944 F. Supp. 2d 244, 256 (S.D.N.Y. 2013) (quoting *Burch v. Pioneer Credit Recovery, Inc.*, 551 F.3d 122, 126 (2d Cir. 2008)); *see also United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 28 (2d Cir. 2016) ("Leave to amend … should generally be denied in instances of futility").

The Generic Defendants' briefing (and supplemental briefing) on the motion to dismiss demonstrates that Plaintiff's earlier complaints failed to allege a viable cause of action against the Generic Defendants. Plaintiff makes no attempt to address the deficiencies in its prior complaints. By Plaintiff's own admission, the goals of the proposed Second Amended Complaint are modest. The new complaint does "not add any new legal theories," but simply "sharpens the contours of pre-existing claims" by, for example, "[d]etailing specifics about the agreements that give rise to [Plaintiff's] claims." ECF No. 150 at 2-3.

Plaintiff does not claim to have pleaded new factual allegations that would cure the defects of the pre-existing legal theories. Neither the Motion to Amend (ECF No. 150), nor Plaintiff's other briefing (ECF Nos. 152, 158) makes any attempt to explain how any new allegations might support or salvage Plaintiff's claims against the Generic Defendants.

For the reasons stated in the Generic Defendants' briefing on the motion to dismiss, neither Plaintiff's operative complaint nor Plaintiff's proffered Second Amended Complaint states a claim against the Generic Defendants. Leave to amend should therefore be denied, and the Generic Defendants should be dismissed from the lawsuit.

II. The Proposed Second Amended Complaint Fails to Plausibly Allege Causation As to Wockhardt, Upsher-Smith, Barr, and Cobalt.

The proposed Second Amended Complaint is also futile because it fails to plausibly allege causation as to Wockhardt, Upsher-Smith, Barr, and Cobalt. In fact, the proposed amendment further highlights why these Generic Defendants should be dismissed from the case. The proposed Second Amended Complaint alleges that "[a]bsent the anticompetitive settlement agreements, generic competition would have commenced sooner" and "because of the Contingent Entry Agreements, no generic launched until on or after July 11, 2015." ECF No. 150-1 at ¶¶ 116, 118. But these allegations are belied by Plaintiffs' admission that Wockhardt, Upsher-Smith, Barr, and Cobalt did not obtain final FDA approval before July 11, 2015—a prerequisite to launching the product regardless of any agreed-upon entry date in the settlement agreements. ECF No. 150-1 at ¶ 118 (alleging only that Dr. Reddy's, Sun, Teva, Orchid, Amneal, Lupin, and Mylan received final approval before July 11, 2015). Thus, the proposed Second Amended Complaint does not plausibly allege that the so-called Contingent Entry Agreements caused Wockhardt, Upsher-Smith, Barr, or Cobalt to delay market entry—on the face of Plaintiffs' allegations, these Generic Defendants did not launch before July 11, 2015 because they failed to obtain final FDA approval to launch by that date.

Indeed, this is consistent with the discovery obtained in the DPP Litigation. Wockhardt, for example, did not receive final FDA approval until September 4, 2015 (almost two months after the agreed-upon entry date) and did not begin selling the product until November 2015 (almost a month after the expiration of Forest's pediatric exclusivity period). *See* EPP ECF No. 466 at ¶¶ 336, 448, 449, Exs. 312, 351 at 51:2-21. It is also consistent with readily ascertainable and publicly available facts long known to IPP, that neither Barr nor Cobalt ever received FDA approval. *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm (enter "memantine

hydrochloride" in search box; then expand "memantine hydrochloride") (showing no approval for the ANDA submitted by Cobalt Laboratories, Inc., No. 90-042, and showing no approval for the ANDA submitted by Barr Laboratories, Inc., No. 90-045); *see also* Stipulation and Order of Dismissal of the Barr Defendants, *Forest Laboratories, Inc. v. Cobalt Laboratories Inc.*, No. 1:08-cv-21, ECF No. 329 (D. Del. May 8, 2009) (stating "the Barr Defendants have withdrawn ANDA No. 90-045" and dismissing all claims).

Thus, as the proposed Second Amended Complaint alleges and the discovery obtained in the DPP Litigation confirms, Wockhardt, Upsher-Smith, Barr, and Cobalt were not delayed in launching generic Namenda *because of* the settlement agreements with Forest. Therefore, the proposed Second Amended Complaint fails to plausibly allege causation as to those defendants and leave to amend should be denied.

Dated: October 23, 2018

Respectfully submitted,

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[1] Electronic signatures provided with consent in accordance with Rule 8.5(b) of the Court's ECF Rules and Instructions.